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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,045	05/12/2000	SE-JIN LEE	JHU1440-1	1418

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EXAMINER	
ANDRES, JANET L	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,045	LEE ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-55* is/are pending in the application.

4a) Of the above claim(s) *1 and 12-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4-11, and 43-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 4 September 2002 is acknowledged. Claims 1, 2, and 4-55 are pending in this application. Claims 1 and 12-42 are withdrawn from consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejections of claim 3 under 35 U.S.C. 102(e) and 35 U.S.C. 112, first and second paragraphs, are withdrawn in response to Applicant's cancellation of this claim.

New Grounds of Rejection/Objection

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 2, 4-11, and 43-55 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 2, 4-11, and 43-55 are drawn to a polynucleotide encoding a GDF-protein. The claimed polynucleotide is not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in

currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

While applicant lists a number of conditions for which the encoded protein might be used (p.5 and 6), the specification does not disclose any activity known to be associated with the encoded protein. Merely listing a number of possibilities is not sufficient to identify or confirm a "real world" context of use; clearly further research would be required to ascertain the function of the encoded protein and the purposes for which it could be used. Similarly, no diseases or conditions with which the protein is associated are disclosed; thus, there is no "specific benefit in currently available form" to be derived from detection of the encoded protein or inhibition of its activity. Thus, further research is required to identify a disease for which it could be used, a disease in which its activity could be beneficially affected, or a disease for which its presence would be diagnostic. See Brenner v. Manson, noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification fails to assert any activity for the encoded protein other than those generally recognized to be attributes of TGF-β. Identifying a polynucleotide as encoding a protein of this family does not endow the polynucleotide with a specific and substantial utility. Proteins of this family are known to function in many different physiological contexts: Massagué (Ann. Rev. Biochem., 1998, vol. 67, pp. 753-791) teaches that "this family comprises a large number of ... factors, each capable

of regulating a fascinating array of cellular processes..." (p. 745). Even those family members identified as GDFs have functions as varied as the promotion of chondrogenesis and the inhibition of muscle growth (p. 755). There is therefore no well-established utility for members of this family; they are involved in many different processes and utility is specific to the individual protein.

5. Claims 2, 4-11, and 43-55 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Claims 43 and 47-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43 and 48-52 are drawn to fragments, or sequences comprising fragments, of greater than 50 or greater than 100 nucleotides in length. There is no support in the specification for these limitations; all that is taught on p. 7 are sequences of at least 15 bases in length. No fragments of greater than 50 or greater than 100 nucleotides are set forth. Claims 43, 45, 47-49, 51, and 52 are drawn to polynucleotides of 98% or 99% homology to the disclosed sequences or fragments thereof. There is no support in the specification for these limitations. 98% or 99% homology is not taught on pages 6 or 7 or elsewhere in the specification.

7. Claims 43, 51, and 52 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, because these claims are drawn to polynucleotides comprising fragments. Applicant has described one polynucleotide sequence, that of SEQ ID NO: 1. One of skill in the art would readily conclude that Applicant was in possession of fragments of this sequence of any size that was set forth in the specification, because one of skill would be able to determine the sequence of all such fragments. However, one of skill would not conclude that Applicant was in possession of sequences comprising fragments that were not required to have any particular function. Such nucleic acids could have any sequence at all attached to the defined fragment: there is no limitation as to the nature of the rest of the molecule and no requirement that it have any particular function. The claims thus encompass polynucleotides that vary widely in structure and function. The one sequence set forth by Applicant is not sufficient to describe a genus that includes polynucleotides of such variable structure and function. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly&Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant specification, there are no other sequences set forth and there are no common structural features or common function specified by which one of skill could identify other members of the

claimed genus. Thus the skilled artisan would not conclude that Applicant was in possession of the genus of polynucleotides comprising fragments of the disclosed sequence.

8. Claims 43, 47, 51, and 52 are rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "biological activity". There is no particular biological activity for GDF-16 defined in the specification; one of skill in the art would not know what activity was intended.

9. Claims 48-50 are objected to because "polynucleotide" is misspelled.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
November 15, 2002

YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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